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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Peter D. Haaland

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EXAMINER

GAKH, YELENA G

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/945,003

Applicant(s)

HAALAND, PETER D.

Examiner

Yelena G. Gakh, Ph.D.

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-28 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,21,22 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-17,19 and 23 is/are rejected.
- 7) ☒ Claim(s) 2,5-17 and 23 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/21/03</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Election of claims 1, 2, 5-17, 19, and 23 filed on 03/08/04 is acknowledged. Claim 18 is cancelled. Claims 3-4, 21-22 and 24-28 are withdrawn from consideration as directed to non-elected species.

Claim Objections

2. Claims 2, 5-17 and 23 are objected to because of the following informalities: the claims are dependent claims, which recite limitations to **the** method of the parent claims (1 and 19). Therefore, "A method" should be changed to "The method" in these claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1, 6-7, 11, 14, 17, 19, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention.

Claim 1 recites "a method for monitoring a biological property" with further recitation of "a biological input". It is not clear from the claim, if the biological property is related to the biological input, since no correlation is recited in the claim. It is also not clear, how "converting the second signal into a human-discernable message" can contribute into "monitoring the biological property", since it is not clear, how this second signal is related to the biological property. The same is true for claim 19 and for claim 17, for which it is not clear, what are relations between all four signals and the biological property to be monitored.

Claim 1 further recites "collecting a biological input", where the "biological input" is defined as "a physiological signal, image, or response" (claim 6). With further recitation of the

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physiological signal (claim 7) as various physical features, such as "acoustic signal", "light reflection", "reflected acoustic wave", "pressure", as well as biological processes, such as "exhalation" or "inhalation", and photographic images, it becomes unclear, what actually is claimed. Moreover, while exhalation being a biological input is understandable, it is absolutely not clear, how inhalation can be a biological input? What particularly is the physiological signal for exhalation or inhalation – its volume, its rate, or its content for specific components? The language of claims 6 and 7 renders them unclear and indefinite.

Claim 11 recites, "wherein the user interface comprises one or more of a computer screen, a key pad, a mouse, etc.". It is unclear, how the user interface can comprise just a keypad, or a mouse, or a speaker, etc. The recitation of claim 11 does not make much sense.

Claim 14 is indefinite, since the expression "physiological signal" is not clear and unambiguous; it is defined in the specification as such a variety of possible physical and biological features, that it makes it unclear, what type of the input port can fulfill the requirement of claim 14?

In claim 17 it is not clear, what is the biological property, for which a second biological input is required? The language of the claim makes it unclear and indefinite.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1, 2, 5-17, 19 and 23** are rejected under 35 U.S.C. 102(b) as being anticipated by any of Schnitzer et al. (US 5,692,497).

Schnitzer discloses "microprocessor-controlled ventilator system and methods". "The central processing unit 22 ("CPU," "microprocessor," or computer) provides overall control of the system 10 to accurately specify the characteristics of the patient's breathing. Accordingly, the system 10 of the invention includes a feedback loop whereby the CPU 22 monitors events

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and characteristics of the patient's breathing, and controls selected actuators to modify such events and characteristics in near real time. By way of example, the CPU 22 controls both proportional valves 24A, 24B so as to control and regulate the flow of gas and O₂, respectively, through the air and O₂ regulators 25A, 25B in response to signals from the flow sensor directional 29 and the oxygen sensor 28. In another example, the oxygen sensor 28 and the flow sensor directional 29 also communicate with the CPU 22 to provide important information about the flow rate and oxygen content of the incoming gases. Sensors 28, 29 and device 26 are part of the flow and oxygen control section 30 which operates to ensure that desirable and/or selected humidified air, with fresh oxygen, is injected to the patient's carina so as to replace or augment the patient's normal inspiration (in ITPV mode, for example, substantially all inspiration is replaced with computer-controlled inspiration and gas injection). If, for example, the flow sensor 29 signaled to the CPU 22 that the flow had changed from the operator-selected level, then the CPU 22 would adjust proportional valves 24a, 24b to make the requisite correction. The same is true of flow/pressure bidirection alert sensor 18 of the signal collection section 32. That is, should the sensor 18 detect an incorrect flow and/or an undesirable pressure, it alerts the CPU 22 through signal line 18A to readjust the flow. A corresponding alert can thereafter be sent by the CPU 22 to a user of the system 10 via signal line 34 connected to an alert device 35, e.g., a LED, buzzer or tactile device" (col. 5, lines 42-68 and col. 6, lines 1-10). This disclosure covers all the method steps recited in the claims 1, 2, 5-17, 19 and 23.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh
3/25/04

A handwritten signature in black ink, appearing to read "Yelena Gakh", is positioned to the right of the typed name and date.